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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,515	05/27/2005	Filippa Brugliera	17922	5939

7590 07/21/2009

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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

MAIL DATE	DELIVERY MODE
07/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,515	BRUGLIERA ET AL.	
	Examiner	Art Unit	
	STUART F. BAUM	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *92-117* is/are pending in the application.

4a) Of the above claim(s) *114 and 115* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *92-113,116 and 117* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 July 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *sequence search result and protein alignment (2)*.

DETAILED ACTION

1. The amendment filed 5/6/2009 has been entered.

RCE Acknowledgment

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/6/2009 has been entered.

3. Claims 92-117 are pending.

Claims 114-115 are withdrawn from consideration for being drawn to a non-elected invention.

Claims 1-91 have been canceled.

4. Claims 92-113 and 116-117, including SEQ ID NO:11 encoding SEQ ID NO:12 are examined in the present office action.

5. Rejections and objections not set forth below are withdrawn.

Drawings

6. Figure 26 is objected to because the text in the dendogram is illegible. Correction is requested.

Claim Objection

7. Claims 92, 100, 103 and 116 are objected to for reciting "selected from the listing consisting of" or "selected from the list consisting of" instead of --selected from the group consisting of--. Correction is requested.

Claim 113, line 2 is objected to for reciting "plant of any one of claims 106" instead of --plant of claim 106--. Correction is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 92-113 and 116-117 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 92, the metes and bounds of "at least about" have not been defined. The term "at least" specifies the lowest acceptable number whereas "about" denotes an approximation of some number. All subsequent recitations of "at least about" are also rejected.

The term "high stringency conditions" in claim 92 is a relative term which renders the claim indefinite. The term "high stringency conditions" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification only provides exemplary conditions. For those artisans skilled in the art, "high stringency conditions" are determined and set depending on the artisan and/or situation, and what one considers high stringency may be low/moderate stringency for another. Applicant should

explicitly state in the claim the specific hybridization conditions. All subsequent recitations of "high stringency conditions" are also rejected.

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 92-113 and 116-117 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated nucleic acid encoding a flavonoid methyltransferase which methylates anthocyanins, said nucleic acid comprising a nucleotide sequence having at least about 70% identity to SEQ ID NO:11, encodes an amino acid sequence having at least about 80% similarity to SEQ ID NO:12 or a nucleotide sequence that hybridizes to any of the above sequences under high stringency conditions or conditions recited in claim 116; or genetic construct, plant, plant part or cells comprising said nucleic acid.

Applicants disclose the isolation of the Torenia flavonoid methyltransferase (FMT) cDNA clone from a cDNA library using the Petunia FMT cDNA clone as a probe (page 72, Example 9). Applicants disclose the Torenia FMT cDNA sequence is set forth in SEQ ID NO:11 and the encoded protein sequence is set forth in SEQ ID NO:12 (*Ibid*). Applicants

disclose the Torenia FMT cDNA sequence exhibits 50% identity with the Petunia FMT cDNA sequence and at the amino acid level, the Torenia FMT polypeptide shares 56% identity and 70% similarity with the Petunia FMT amino acid sequence. Applicants disclose the Fuchsia FMT clone of SEQ ID NO:43 encoding the Fuchsia FMT protein of SEQ ID NO:44 (page 105, 1st full paragraph). Applicants disclose the Fuchsia FMT protein exhibits 67% and 82% similarity with the Petunia and Torenia FMT proteins, respectively.

The Office contends the state-of-the-art discloses a nucleic acid sequence that encodes a polypeptide exhibiting 82% identity and 91% similarity with Applicants' SEQ ID NO:12 but has caffeoyl-CoA O-methyltransferase activity (sequence search results included) (Pommerrenig et al., 2006, NCBI Accession Number AM159091). Given the disclosure of a polypeptide having high sequence identity or sequence similarity to Applicants' invention but possessing a different activity than Applicants' FMT, and given Applicants' broad claims, a showing of possession requires a teaching of essential regions of FMT proteins having the requisite activity and a description of polynucleotides that hybridize to SEQ ID NO:11 under the specified conditions. Applicants have not disclosed essential regions of polypeptides having FMT activity operable in Applicants' invention nor a description of polynucleotides that hybridize to SEQ ID NO:11 or sequences that encode polypeptides having at least about 80% similarity to SEQ ID NO:12 and possessing the required activity.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the

structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences encoding a FMT protein falling within the scope of the claimed genus of polynucleotides which hybridize to and which encode a polypeptide having at least about 80% similarity to SEQ ID NO:12 and which have the required activity for Applicants' invention. Applicants only describe Petunia, Fuchsia and Torenia cDNA sequences of SEQ ID NO:4, 11 and 43 and the encoded proteins of SEQ ID NO:5, 12 and 44, respectively. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the FMT protein, it remains unclear what features identify a Torenia FMT protein. Since the genus of FMT proteins has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Applicant's arguments filed 5/6/2009 have been fully considered but they are not persuasive.

Applicants contend the specification has adequately described relevant identifying characteristics of the genus (page 13 of Remarks, top paragraph). Applicants contend that the structural description is satisfied by nucleic acids that either hybridize to a specified sequence under high stringency conditions or share specific sequence homology to SEQ ID NO:11 or SEQ ID NO:12. Applicants contend that a functional limitation is presented that requires the selected sequences to encode a protein having FMT activity, i.e., it methylates anthocyanins (*Ibid*). Applicants contend they have disclosed several FMT-encoding clones from various plants that share significant sequence similarities (page 13 of Remarks, 2nd full paragraph).

The Office contends the state-of-the-art teaches a nucleic acid sequence that encodes a protein falling within the claimed genus but has a different activity compared to Applicants' invention. In fact, the encoded protein exhibits over 80% identity and over 90% similarity to Applicants' SEQ ID NO:12. Comparing the protein alignment of SEQ ID NO:12 and the protein from NCBI Acc No. AM159091 with the protein alignment of SEQ ID NO:12 and SEQ ID NO:5, there are amino acids that are conserved between all three proteins, yet NCBI Acc No. AM159091 has a different activity (protein alignments are attached). The Office contends Applicants have not disclosed which amino acids are conserved and required for the activity of the claimed invention.

Enablement

10. Claims 92-113 and 116-117 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to an isolated nucleic acid encoding a flavonoid methyltransferase which methylates anthocyanins, said nucleic acid comprising a nucleotide sequence having at least about 70% identity to SEQ ID NO:11, encodes an amino acid sequence having at least about 80% similarity to SEQ ID NO:12 or a nucleotide sequence that hybridizes to any of the above sequences under high stringency conditions or conditions recited in claim 116; or genetic construct, plant, plant part or cells comprising said nucleic acid.

Because of the indefiniteness of "high stringency conditions" as discussed above, the Office interprets "high stringency conditions" to mean any conditions, including low stringency conditions.

Applicants disclose the isolation of the Torenia flavonoid methyltransferase (FMT) cDNA clone from a cDNA library using the Petunia FMT cDNA clone as a probe (page 72, Example 9). Applicants disclose the Torenia FMT cDNA sequence is set forth in SEQ ID

NO:11 and the encoded protein sequence is set forth in SEQ ID NO:12 (*Ibid*). Applicants disclose the Torenia FMT cDNA sequence exhibits 50% identity with the Petunia FMT cDNA sequence and at the amino acid level, the Torenia FMT polypeptide shares 56% identity and 70% similarity with the Petunia FMT amino acid sequence. Applicants disclose the Fuchsia FMT clone of SEQ ID NO:43 encoding the Fuchsia FMT protein of SEQ ID NO:44 (page 105, 1st full paragraph). Applicants disclose the Fuchsia FMT protein exhibits 67% and 82% similarity with the Petunia and Torenia FMT proteins, respectively. Applicants disclose the transformation of rose with a vector comprising a Viola F3'5'H gene and the Torenia FMT or the Petunia FMT, both of which operably linked to the 35S promoter (page 82, lines 25-28). Applicants disclose the transformed rose plants produced flowers whose petals were dark pink to red-purple, instead of apricot (page 98, 2nd full paragraph). Applicants disclose the Petunia FMT was not as effective as the Torenia FMT (page 98, 1st full paragraph). Applicants also disclose transforming another rose cultivar, i.e., lavande, which produced similar results (page 99).

Applicants have not reduced to practice their invention. Applicants have not disclosed any examples in which only the FMT gene of SEQ ID NO:11 is transformed into a plant and wherein the transformed plant exhibits a change in flower color. All of Applicants' examples disclose plant transformation with both a Viola F3'5'H gene and a FMT gene. In addition, Applicants disclose that the Petunia FMT gene was not as effective as the Torenia FMT, suggesting that not all FMT genes are operable in Applicants' invention.

The state-of-the-art is such that one of skill in the art cannot predict which nucleic acids that encode a protein at least about 80% similar to SEQ ID NO:12 will encode a protein with the same activity as a protein encoded by SEQ ID NO:11. This is particularly true given the

teachings of Pommerrenig et al as discussed above. The prediction of protein structure from sequence data and, in turn, utilizing predicted structural determinations to ascertain functional aspects of the protein, is extremely complex, and the positions within the protein's sequence where amino acid substitutions can be made with a reasonable expectation of maintaining function are limited (Bowie et al, Science 247:1306-1310, 1990, see especially page 1306). Proteins may be sensitive to alterations in even a single amino acid in a sequence. For example, the replacement of a glycine residue located within the START domain of either the PHABULOSA or PHAVOLUTA protein receptor with either an alanine or aspartic acid residue, alters the sterol/lipid binding domain (McConnell et al, Nature 411 (6838):709-713, 2001, see especially page 710, left column, 2nd paragraph).

Applicants claims are drawn to nucleic acid sequences that hybridize to SEQ ID NO:11 under moderate or low stringency, but the state-of-the-art teaches isolating DNA fragments using stringent hybridization conditions, does not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe. Fourgoux-Nicol et al (1999, Plant Molecular Biology 40 :857-872) teach the isolation of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65^0C (page 859, left column, 2nd paragraph). Fourgoux-Nicol et al also teach that the probe and isolated DNA fragment exhibited a number of sequence differences comprising a 99bp insertion and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotide mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of

contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2).

Applicants have not disclosed how one makes or isolates any of the sequences that are encompassed by Applicants' broad claims. Applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences. Therefore, the instant specification fails to provide guidance for which amino acids of the protein encoded by SEQ ID NO:11 can be altered, the type of alteration, and which amino acids must not be changed, to maintain activity of the encoded protein. The specification also fails to provide guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional protein. This is especially true given the teachings of Pommerrenig et al, as discussed above.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SEQ ID NO:11as probes or by designing primers to undisclosed regions of SEQ ID NO:12 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed produce a plant whose flowers have an altered flower color as compared to a wild-type plant.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Applicant's arguments filed 5/6/2009 have been fully considered but they are not persuasive.

Applicants contend it would not take undue experimentation to practice the claimed invention because the specification discloses that nearly 200,000 clones from a Torenia library were screened using a Petunia probe under low stringency conditions and only 20 clones were tested positive (page 9 of Remarks, bottom paragraph). Applicants contend the specification discloses an assay for identifying an FMT enzyme that methylates anthocyanins (page 10 of Remarks, 2nd full paragraph).

The Office contends Applicants' claims do not recite using the Petunia probe to identify the claimed invention. Applicants' claims are drawn to any sequence encoding a protein having 80% similarity to SEQ ID NO:12 and possessing FMT methyltransferase activity that methylates anthocyanins. Applicants have also not disclosed that SEQ ID NO:12 by itself can produce the desired results (see above). Given the state-of-the-art as discussed above, and the lack of teaching of conserved domains or amino acids that are specific to FMT methyltransferases operable in Applicants' invention, and given the unpredictability as discussed above, and the lack of working examples just using SEQ ID NO:12, undue trial and error experimentation would be required to practice the claimed invention.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 92, 95-110 and 116-117 are rejected under 35 U.S.C. 102(b) as being anticipated by Gauthier et al. (GenBank Sequence Accession No. U16794, pages 1-2, published November

8, 1995) taken with the evidence of Joshi et al. (Plant Molecular Biology, 37:663-674, 1998, Applicant's IDS).

The claims are broadly drawn to an isolated nucleic acid comprising a sequence of nucleotides encoding a flavonoid methyltransferase (FMT), which FMT acts on anthocyanin molecule wherein the nucleic acid hybridizes under high stringency conditions to a nucleic acid encoding SEQ ID NO:12 or a nucleic acid encoding a protein having at least about 80% similarity to SEQ ID NO:12, or wherein the FMT is a class I S-adenosyI-L-methionine-O-methyltransferase (SAM-OMTs), or wherein the FMT is 3'FMT or 3'5'FMT, or wherein the anthocyanin molecule is a derivative of delphinidin or petunidin, or wherein the anthocyanin molecule is delphinidin 3-glucoside, or wherein methylation of an anthocyanin molecule results in the production of a petunidin derivative, or wherein said nucleic acid molecule comprises a nucleotide sequence capable of hybridizing under conditions specified in claim 116(iii).

Because of the indefiniteness of "high stringency conditions" as discussed above, the Office interprets "high stringency conditions" to mean any conditions, including low stringency conditions.

Re: claim 116 recites a wash condition in 0.2-2XSSC which the office interprets as 2X SSC which is considered a low stringency wash.

Gauthier et al. disclose a cDNA clone comprising a genetic construct, which comprises a cDNA sequence encoding 3' flavonoid O-methyltransferase protein (pg 2). The reference further discloses that said cDNA clone was isolated from cDNA expression library (Uni-Zap XR, see pg 1 under features, line 32). The reference further discloses that said library was prepared from Chrysosplenium americanum (pg 1, line 27). The reference also discloses 3' flavonoid O-

methyltransferase activity of the protein disclosed in the reference (pg 1, lines 38 and 43, experimental results).

It is important to note that since cDNA clone disclosed in the reference was isolated from a cDNA expression library, it would thus inherently comprise other components of a genetic construct, such as, a promoter and transcription termination signals.

Although Gauthier et al. do not explicitly disclose that their FMT protein is a class I S-adenosyI-L-methionine O-methytransferase which acts on anthocyanin molecule, such a feature is inherent to the FMT protein disclosed by Gauthier et al. This is further evidenced by Joshi et al., who disclose a 3' flavonoid O-methyltransferase sequence (GenBank accession No. U16794, pg 665, table 1) having 100% sequence identity to Gauthier et al. FMT, and which methylates (same as "acts on") anthocyanin (flavonoids) substrates. Joshi et al. also disclose that their 3' flavonoid O-methyltransferase is a S-adenosyI-L-methionine O-methyltransferase. See in particular, page 664, 2nd paragraph of right column; page 665, table 1; page 665 tables 1-2; page 668, table 4; pages 670- 671, figure 2).

Although Gauthier et al. do not explicitly disclose methylation property of 3' flavonoid O-methyltransferase on anthocyanins substrates, such as, delphinidin, delphinidin-3-glucoside (derivative of delphinidin), petunidin or petunidin derivatives, such a property would be inherent to the enzymatic activity of Gauthier et al. 3' flavonoid O-methyltransferase, unless the Applicant provides evidence to the contrary.

Accordingly, Gauthier et al. anticipated the claimed invention.

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Stuart F. Baum/
Stuart F. Baum Ph.D.
Primary Examiner
Art Unit 1638
July 15, 2009